r26m r36m

Middle ear analyser

QUICK USER'S HANDBOOK

CE 0051

Kamplex

Release history

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R26M/R36M Middle ear analyzer manifactured for Intricon UK Ltd by:

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IMPORTANT NOTICES

Kamplex® thanks you for having purchased one of its medical devices!

Kamplex® hereby advises that in order to ensure optimized device performance and full customer satisfaction, prior to proceeding with device installation and use you are kindly requested to carefully read and understand all the notices and warnings given in this User's Handbook, as they provide important directions on device safety, care and maintenance.

Carefully store this manual away in a safe place for each future consultation.

This device has been manufactured and factory tested, fully compliant to product standards and regulations and has been delivered from its manufacturing premises in perfect technical safety conditions. Once the device has been removed from its packaging, please check to ensure it has not been damaged and that no parts are missing.

In case of any doubt, please do not use the device and either contact your Kamplex Dealer, or e-mail the Customer Support Service directly at support@kamplex.co.uk.

If the device drops or falls accidentally and/or is subject to violent impacts, it may also undergo hidden and/or invisible damages, incurring in hazardous device operation.

Operating options and Scope of use

The R26M/R36M measuring unit provides for clinical middle ear analyzer.

The comprehensive middle ear analyzer test capabilities include:
Tympanometry, Acoustic Reflex testing (ipsilateral and contralateral), Acoustic Reflex latency measuring, Reflex Decay and Grow-DLI testing, Eustachian Tube Functionality (for both intact and perforated tympanic membrane), a series of quick tests with configurable protocols, Non-Acoustic stapedial reflex testing.
R26M-PT and R36M-PT can perform Multifrequency Tympanometry with 678 Hz, 800 Hz and 1000 Hz probe tones.

Use of the unit is reserved to audiologists, medical and technical hearing aid and conservation professionals and audiology specialists.

The unit is meant for use in clinical environments and at low ambient noise levels. For some types of tests (audiometry), very low ambient noise levels are required.

During patient testing processes, operators are required to exercise maximum care and attention.
An operating ambient temperature ranging between 15 and 35 °C (59 - 95 °F) is recommended.

Safety warnings and precautions

Any possible modification and/or alteration to this device is prohibited, without prior authorization thereto by the Manufacturer.

In the event that the R26MC/R36M is connected to other devices having individual, external power supply source, it is necessary to test, under the technician's responsibility, the compliance of the overall system to the EN 60601-1 Standard Provisions. Should the implementation of any insulation or grounding devices be required to meet conformity, said devices must also conform to Standard EN 60601-1.

When using the middle ear analyzer probe, ensure that suitably-sized tips are used and check that they are perfectly ear-sealed and do not cause the patient any discomfort. Said tips are to be selected from the set of ear tips on supply with the device. Use of a new tip for each patient is compulsory.

During test performance, always check the unit's stimulus frequency intensity setting prior to starting testing. This is to ensure application of acceptable patient stimulation intensity levels.

Prior to starting a new patient, proceed with cleaning the sections of the transducers that come into direct contact with the patient (e.g. earphone pads). All cleaning operations need to be performed using an appropriate antiseptic solution, compliant to the instructions provided directly by the antiseptic product Manufacturer. Please also consult the maintenance and cleaning section in this manual. The R26M/R36M device is not suitable for use with flammable anesthetics. The R26M/R36M is furthermore not provided with protection against the ingress of liquids: the possible penetration of drops and/or liquid spray substances may result in serious damages occurring to the unit.

The unit must always be used with the unit's own transducers, provided on-supply by the Manufacturer. Please be advised that the unit has been calibrated for use with the transducers that are supplied. If they are replaced, recalibration of the unit is necessary.

Although the unit is compliant to the EMC (electromagnetic compatibility) regulations currently in force, prevention of unit exposure to other electromagnetic sources such as cell phones is highly recommended. Should the unit be in the vicinity of or placed alongside other devices, prior to using the unit please ensure that there are no interferences between the two systems.

Controls and components

front section

1. 7", color graphic TFT display module.
2. Built-in thermal printer.
3. KNOB (dB / daPa): the knob enables the manual pressure adjustments and selection of the items on the menu pages.
4. F1.....F6 function keys: enable execution of the function displayed on the bottom section of the screen frame, just above the corresponding keys. Said functions will vary according to the type of test being run or the menu that is displayed.
5. TEST: when in testing mode, this key enables return to the main selection page.
6. ENTER: key for accessing the tests from the main menu.

7. ARROW KEYS: are used for the various selections provided on the menu pages.
8. SIGNAL: manual start of reflex tests is enabled (via CH1) and, once the function is enabled, manual pressure can be reset (via CH2).
9. FREQUENCY: keys enable selection of the signal frequency sent to the transducers.
10. IPSI: this key is used to select the probe as a transducer for the transmission of stimuli during stapedial reflex detection tests.
11. CONTRA: this key is used to select the contralateral transducer for the transmission of stimuli during stapedial reflex detection tests.
12. SIDE: key enables selection of right or left.
13. START/STOP: this key enables start/stop of some of the test options.
14. PRINT: if pressed from the main selection page, this key enables printing of all the tests performed (via thermal printer, or by creating a pdf report), otherwise printout of a single test is possible if the key is pressed directly from the test page (with printout via the built-in thermal printer).

Connectors and components

rear section

15. CONTRA: 6.35 mm stereo jack output for contralateral stimulation transducer connection, during stapedial reflex detection testing (DD45, TDH39 or Insert)
16. PROBE: 15 pin Cannon connector for hook-up of the middle ear analyzer probe
17. PRESSURE: junction connector for connection of the middle ear analyzer probe pressure tube.
18. FOOT SWITCH: no longer in use
19. : USB host port for hook-up of a USB keyboard and/or an external USB data storage pen drive
20. : USB slave port for PC communication and data transfer
21. ON-OFF switch: on-off switch with fuse holders and mains power supply cable connection

Installation

Prior to switching the device on, please proceed with connecting the transducers required for testing.

The following is required for performance of the main tympanometry tests:
the Probe plus the DD45 or TDH39 transducers for contralateral stimulation.
Connect the power supply cable to the device, checking to ensure that the cable is turned correctly to connect to the power mains, then press on the rear switch (21) to power the device on.

According to the EN60601-1 Standard provisions, the device falls under class 1. It is therefore necessary that the power grid, which it is connected, is provided with a grounding connection.

Parameter Setups

Once the device is on, proceed with the principal settings involved with test performance.

Press the F1 key (4) to access the setup menu. Via the adjustment knobs (3) or the down arrow, select the PARAMETER SETUP function and then press ENTER (6). Use the side arrow keys (7) to select the various options and/or to change selected options. Use the down arrow key to move to the next setup function.

On SETUP page, available options are grouped in separate sections.

Device general parameters
Language: changes the end-user interface language.
Date and time: changes the system date and time that is currently displayed.
Contra Reflex: selects the type of transducers to be used for contralateral stimulation (DD45, TDH39 or INSERT).
Reflex Up-Down: changes display of the patient response during Reflex testing.
Autorun: if enabled, starting of the middle ear analyzer tests is automatic.
Pump reset key: if enabled, it provides for manual pressure reset in middle ear analyzer tests (Signal CH2).
Manual Reflexes: this option is only available for the Reflex test in manual mode. If set on "level", by pressing START (13), the test will start and the stimuli will be emitted in sequence with varying the level but not the frequency. If set on "frequency" the stimuli sequence will be executed varying the frequency but maintaining the level unvaried.
Tymp Protocol: 2 options available: Adult and Children. "Children" is the fastest way to execute the test, both protocols guarantee the same accuracy.
Leakage Test: the leakage test parameters can be changed to set the appropriate sensitivity to check the probe sealing into the ear.
Reflexes Threshold: the automatic reflex recognition sensitivity can be settled to different levels.
Single Graph: if active, the right and left tympanogram reports are printed separately with the internal thermal printer. (R36M or R36M-PT only)

The setting entries can be confirmed by pressing F5 (4).
Time and date settings can be stored by pressing F3 (4).
Press F1 to return to the main Test Selection page.

Performance of middle ear analyzer tests

Once the device has been powered on, middle ear analyzer tests can be selected on the display, by using the arrow keys (7).
Prior to performing the tests, check that the probe is connected to the device via the appropriate connectors on the rear panel (16) and (17). The device will display a message if the probe is not connected to the dedicated port (16).
Once selected, to access the test page press the ENTER (6) key. It is also possible, in Test Selection page, to select a "priority" Test by pressing on softkey F2. Please, follow the displayed instructions to complete the setting.

Preliminary operations

Compliance calibration (probe 226 Hz and probe HF)
Prior to proceeding with the tests we suggest that a daily compliance calibration is performed. To proceed, press F1 (4) from the initial test selection page, select "Compliance Calibration" and then press ENTER (6). To execute the compliance calibration, put a yellow tip onto the probe. Using the block with the calibration cavities supplied with the device, follow the instructions that appear on the display inserting the probe in the calibration cavity and pressing F5 (softkey "CONFIRM"). At the end of the calibration (indicated by an OK on green background on the display), press F1 twice to return to the initial test selection page.
For -PT models, with -HF probe (multifrequency), it is possible to calibrate a single frequency following the same procedure or to calibrate all frequencies in sequence by pressing AUTOMATIC (F6) and follow the instructions that appear on the display, inserting the probe in the calibration cavity and pressing again AUTOMATIC (F6).
For insertion of the probe into the patient's external auditory ear canal, it is necessary to fit the probe with an end tip that is suitably sized to fit the auditory ear canal being tested. This to ensure optimized pressure sealing. Exclusive use of the tips supplied by Kamplex and provided on-issue with the device is highly recommended.

Tympanometry 226 Hz
Choose test by selecting ENTER (6) . Selection of the ear the probe is to be inserted in is entered via the SIDE (12) key. All the test performance parameters can be altered directly via the test page: start and stop pressure values via softkeys F1 and F2 (4), pressure generation system speed via softkey F5 (4).
Test START is entered by pressing the START/STOP (13) key. If the Autorun function is active (via the setup menu), the test starts automatically once the system detects a steady auditory ear canal value reading. Once testing of the first ear is finished, remove the probe. To run the test in the second ear, press the SIDE (12) key and then position the probe into the second ear. If test is interrupted to restart the test, press the START/STOP (13) key. To enable a new test to start automatically when the Autorun function is active, hold the probe out of the test ear for the time necessary for the "Probe Open" message to show up on display before placing it into the test ear. Tympanometry can be executed by manually varying the pressure generated inside the ear. To execute the tympanometry in manual mode, select the test and press F6 (exam management) followed by F4 (Manual). To vary the pressure use the Channel 2 knob (3).

Reflex detection tests (REFLEX, DECAY, ARLT)
For all the above tests that request the output of acoustic stimuli to the patient, reflex detection can be performed in three different mode options (manual, automatic and auto threshold), which can be selected via the MODE (4) softkey.
Manual mode = Performance of the test is completed at the values the tester chooses. The result is interpreted by the audiologist.
Automatic mode (screening reflex) = The test is performed in according by the preset parameters. You can perform up to 8 tests for each side (ipsi or contra) across the frequencies. Results are interpreted by the audiologist.
Autothreshold = The device automatically performs the test in according by the preset parameters and the result is determined in according by which sensitivity is selected in the SETUP.
For all the foregoing options, tests can be performed either at 0 pressure or after automatic peak flexibility resolution (peak pressure). Relative selection can be entered via the PEAK (4) softkey.

Some of the test performance parameters can be altered directly from the test page itself. The same parameters or other parameters can be set via the parameters page, which can be accessed via the TEST MANAGEMENT > PARAMETERS (4) softkey.
In the manual mode option on the test page, the ear to be tested is selected using the SIDE (12) key, the IPSI and CONTRA (10) and (11) keys are used for selection of the transducer the stimulus needs to be sent to, the stimulus frequency is selected via the FREQUENCY (9) keys and the stimulus intensity is adjusted by using up/down arrowheads.
Using the arrow keys right and left (7) it is possible to select the screen box, among the screen boxes present on display, that the detected reflex data is required to be displayed in.
The test start command can be entered either via the SIGNAL (8) key or via the START/STOP (13) key. In the first option, one single stimulus is transmitted and the corresponding reflex is recorded while in the second option provides for performance of the complete test.
In the reflex tests in manual mode, it is possible to vary manually the pressure by using the knob (3).

Decay
Reflex decay testing can be completed by selecting the test under the test menu. Some of the test performance parameters can be altered directly from the test page. The same parameters or other parameters can be set via the parameters page, which can be accessed via the TEST MANAGEMENT, PARAMETERS (4) softkey.
To perform an acoustic threshold Decay test at a specific stimulus frequency, an acoustic reflex test at the same frequency must be previously executed, otherwise the device will display a warning.

ETF for intact and perforated tympanic membrane
The only parameter that can be altered for this type of test is the pressure generation speed during the ETF test (with intact tympanic membrane), which can be adjusted directly on the test page by acting on the SPEED (4) softkey. The START command for both tests can be entered via the START/STOP (13) key, or they will run automatically if the Autorun function is active. After 1st run instruct patient to swallow liquid, then select CONTINUE (F4). A 2nd measurement will be taken. Instruct patient to swallow liquid, then select continue (F4). A final measurement will be taken. Interpretation is completed by the audiologist.

Non acoustic
Test with graphical representation similar to the Decay test. Test length can be either of 10 or 20 secs. The test is conducted without acoustic stimulation, therefore the stapedial reflex can be stimulated by a tactile or ocular contraction with light air blows. This test can be adopted to investigate subjects with Patulous Eustachian Tube. To change the length of the test press F5. The test can be conducted at 0 daPa or at tymp peak (maximum mobility) performing a tympanogram by pressing F1 PEAK (Zero or Auto).

Quick tests
Three rapid execution tests can be selected from the test selection page: Quick check, Quick screening, Quick decay. All three tests include the execution of a tympanogram and subsequently tests for the detection of the stapedial reflex performed at the pressure at which the peak has been detected during the tympanogram . For all tests the various execution parameters can be changed by pressing F6 > F5. In the Quick check the stimuli for the reflexes will be emitted at the intensity selected in the parameters window, in the Quick Screening a reflex threshold research will be carried out with successive stimulations with increasing intensity, the Quick decay will be performed using the same method of the screening plus the decay test. The " Children" mode can be activated in Quick Check by pressing F5. This feature, designed for use with children, displays a sequence of colored images on the screen that are meant to attract the child's attention while performing the examination. When the image sequence is running, the test will be run in background, giving the operator the necessary information.

Growth - DLI
Similar to the Decay test, once the stimulus is issued at a fixed intensity, a series of short increment stimuli at variable intensity can be sent to the subject in order to highlight a further contraction of the stapedius. All controls are similar to those seen in the previous test for reflex detection.

HF tympanometry (only for R26M-PT and R36M-PT)
Similar in execution and controls to the 226 Hz Tympanometry.
Three separate graphic areas are available to perform three different tympanograms at different probe tone frequencies: 678 Hz, 800 Hz and 10000 Hz. The three tympanograms can be run with pressure generation in automatic or in manual mode (only Y curve shown in manual mode).
For each tympanogram, at the end of the test, three curves will be displayed shown as Y (admittance), B (susceptance) and G (conductance) useful to describe more fully the behavior of the ear when probe tones, next to its resonant frequency, are used.
In tympanometry with 1000 Hz tone, the CHILDREN mode is available, as described in the Quick check.

Loading paper in the thermal printer

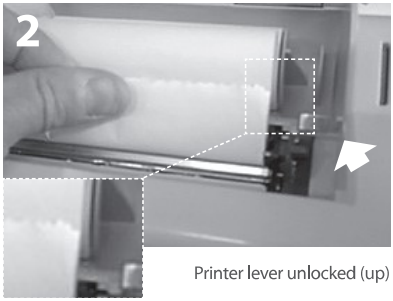
Lever printer locked in print position (down).

1. Turn on the Kamplex device.

2. Open the printer lid. With the printer lever locked in print position (down), put the paper into the roller as shown in Picture 1, and then press the F6 key to advance the paper.

3. Once the paper is through to the other side of the roller, unlock the printer lever and manually position the paper so that the edges of the two sides are aligned as shown in Picture 2. Once you have the alignment, lock again the printer lever in print position (down).

4. Lower a little the printer lid, Insert the paper into the proper slot on the lid and close it.



Printer lever unlocked (up)

Print management and .pdf report

After performing the test, a summary can be printed via the built-in thermal printer, by generating a report in pdf sent directly to a USB stick connected to the instrument, or by downloading to the software manager. An external USB keyboard to edit data directly from the device is available as optional.

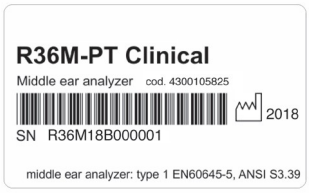
Print Summary by thermal printer
When on the page of any of the test, press the TEST button (5) to move in one of two pages SELECTION TEST. Press PRINT key (14) to access the management page printing.
Using the up and down arrow keys to highlight texts you do not want to print and deselect them by pressing ENTER (6). Always using the up and down arrow keys move through the fields (editable via the external USB keyboard). Once you have highlighted the scope for the type of release (pdf or thermal), using the left and right arrow keys select "Print Thermal" and press the PRINT key (14). The test will be printed in sequence the thermal printer.

Print summary reports via pdf
Repeat the above operations above until the selection of the type of printing. Select the item "Print PDF" and press the PRINT key (14). A pdf file will be saved in the root of the USB stick and appointed with the first three characters of the name followed by the patient's current date and time (if no patient name was added to the file will be named with "unknown" followed by the current date and time).

Custom logo and header
A custom logo can appear on the report pdf, from the root of the USB stick, there must be a folder named "images" within an image file with the desired logo. The image file must have a .jpg extension, be named **Company_logo.jpg** and be 200 x 50 pixels in size.
In addition to the logo, so that it can appear on the report pdf a custom text with user data of the instrument, in the same images folder, located on the USB stick, there must be a file text called **Company_data.ini** showing the desired text (4 lines of text). Once the USB stick is connected to the instrument the image and the text will be imported directly into the .pdf template.

Main labels

Product identification label
(located on the underside)



Label located in the power supply section

CE 0051
RoHS
POWER REQUIREMENTS
110 - 240V ~ 50/60 Hz 40VA
FUSES: 2 x T 1 A L 250V
Manufactured for Intricon UK Ltd by
M.R.S. srl via C. Battisti 134, 24025 Gazzaniga (BG) Italy

Symbols present on the device

	ON (mains power supply)
	OFF (mains power supply)
	Alternating current
	Please consult the operating instructions
	Application of type B components
	Please consult the manual for instructions on which transducers to select for connection.
	This symbol placed on the device indicates that when it is scrapped, the device must be subject to "separate municipal collection". The User is therefore required to deliver the scrapped device (either directly or indirectly) to the separate waste collection canters set up for the purpose by the local or municipal waste management organizations, or to give the device back to the dealer against purchase of a new, equivalent type of device.
	RoHS mark ensuring compliance to RoHS Directive
	Together with the relative name and address, this symbol identifies the device Manufacturer.
	CE mark ensuring compliance to the MDD 93/42/EEC Directive - Notified certification body no. 0051 (IMQ).
	Year of production of the device
	USB Host port
	USB Slave port

Messages that may show up

Message on display	When it appears	Message type	Meaning	Troubleshooting
RUNNING TEST	It appears during performance of middle ear analyzer tests	System message	It means that the test is being performed	No action is required
PRESSURIZE	It appears during middle ear analyzer tests when a pressure generation request is entered	System message	It means that pressure is being generated in the cavities the probe has been inserted into	No action is required
PUMP RESET	It appears during middle ear analyzer tests when the pump is reset back to default status	System message	It means that the pump has been reset back to default status	No action is required
RUNNING TYMP	It is highlighted in a yellow box during middle ear analyzer reflex testing when an automatic peak compliance detection request has been entered	System message	It means that the tympanometric graph is being plotted	No action is required
PEAK SEARCH	It is highlighted in a yellow box during middle ear analyzer reflex testing when an automatic peak compliance detection request has been entered	System message	It means that the device is automatically running a peak compliance detection process	No action is required
PROBE OPEN	It appears during middle ear analyzer tests when the cavity values recorded by the device are higher than the maximum value that is acceptable for test performance	Error message	It means that the cavity value read off by the device is higher than the maximum value that is acceptable for test performance	Check to ensure that the probe is inserted with an acceptable cavity value and that the cone-shaped end section of the actual probe has been firmly closed
PROBE CLOSED	It appears during middle ear analyzer tests when the cavity values recorded by the device are lower than the minimum value that is acceptable for test performance	Error message	It means that the cavity value read off by the device is lower than the minimum value that is acceptable for test performance	Check to ensure that the probe is inserted with an acceptable cavity value and that probe exit is not obstructed in any way
WAIT	It appears during middle ear analyzer reflex testing, in the time gap between each stimulus emission	System message	It means that it is necessary to wait for the next stimulus	No action is required

NOT FOUND	It appears during middle ear analyzer reflex testing, when the automatic peak detection function has been set but the peak is not detected	Error message	It means that during plotting of the tympanometric graph, the compliance variation levels were not enough to allow the device to detect the point in which to perform the reflex test	Check to ensure that pressure is being generated by the device; check that the probe exit is not obstructed; check to ensure that the probe has been inserted into the ear and not into a rigid cavity; the message may occur due to a pathology by the patient being tested: in case of doubt, please repeat the test on a norm-auditory subject.
LEAKAGE TEST	It appears during middle ear analyzer testing at the set start pressure, prior to plotting of the tympanometric graph	System message	It means that the device is running an automatic pressure maintenance check prior to performing the test.	No action is required
LEAKAGE	It appears during middle ear analyzer tests when a pressure leakage is detected	Error message	It means there is a pressure leak in the device's pressure circuit	Check to ensure that the probe has been well inserted into the test cavity; ensure that the cone-shaped section of the actual probe has been firmly closed; check that the dimension of the tip being used is appropriate for the cavity the probe has been inserted into.
NO REFLEX	It appears during threshold tone decay testing, when a prior, valid stapedial reflex performed previously at the same frequency, is missing	Error message	It means that no valid reflex was found during previous reflex testing, at the same frequency set for the decay test	If this is not due to pathology by the patient being tested, it is necessary to perform a reflex test for the frequency levels and stimulation side that the decay test must be performed on
TEST NOT COMPLETED	It appears during middle ear analyses when the tympanometric graph has not been completed correctly	Error message	It means that the tympanometric graph has not been plotted correctly and the test has therefore been interrupted	Check to ensure that there aren't any pressure system leaks
POSITIVE PRESSURE	This message appears during performance of the ETF testing for non-perforated eardrums, whilst positive pressure is being generated	System message	It means that positive pressure is being generated for test performance	No action is required
NEGATIVE PRESSURE	This message appears during performance of the ETF testing for non-perforated eardrums, whilst negative pressure is being generated	System message	It means that negative pressure is being generated for test performance	No action is required

INSTRUCT PATIENT	It appears during performance of the ETF testing for non-perforated eardrums	System message	It means that the patient is required to swallow, when instructed by the operator to do so	No action is required
PROBE NOT CONNECTED	It appears during middle ear analyzer testing, if the probe is not connected up to the device	Error message	It means that the probe is not hooked up to the appropriate connector on the device's rear panel	Connect the probe up to the correct rear-panel connector
AUTORUN CHECK	It appears when middle ear analyzer tests are performed when the Autorun function has been activated	System message	It means that the test is being performed with the Autorun function activated	No action is required - if the Autorun function is not wanted, it can be deactivated via the Setup menu
DO YOU CONFIRM ?	This query appears after entry of plot cancellation or parameter change requests	System message	It means that a plot cancellation or a parameter change request has been entered	Press either the YES or the NO when the query appears
CHANGE CALIBRATION DATE ?	This message appears at the end of the device calibration procedure, once the "SAVE" softkey has been pressed and values have been changed.	System message	It provides the option of updating periodic calibration dates	Press either the YES or the NO when the query appears
INSERT PROBE INTO THE SPECIFIED CAVITY	This message appears when on the Compliance Calibration page	System message	This message refers to the cavity value displayed on the Calibration page, that it is necessary to insert the probe into for calibration performance	Insert the probe into the test cavity as displayed
PRESS CONFIRM/AUTOMATIC KEY	This message comes up on the Compliance Calibration page the instant in which the probe is inserted into the specified cavity	System message	it provides instructions that need to be followed in order to proceed with compliance calibration	Press the confirmation key to calibrate selected probe tone frequency or automatic key to calibrate all probe tone frequencies (PT models)
CHECK CAVITY	This message is given on the Compliance Calibration page if the probe is not inserted into the displayed cavity	System message	It means that the probe has been inserted into the wrong cavity	Proceed with inserting the probe into the correct test cavity, as displayed
READ VALUE (ml)	This message is given on the Compliance Calibration page, at the end of the calibration process	System message	It means that the value that is displayed is the real-time value reading by the device	No action is required
INSERT PROBE INTO THE 2cc CAVITY	This message appears on the ARLT Calibration page, if the probe is not inserted into the 2cc cavity.	System message	You are instructed to insert the probe into the 2cc cavity in order to perform calibration	Proceed with inserting the probe into the 2cc cavity
PRESS RUN TO PERFORM CALIBRATION	This message appears on the ARLT Calibration page, when the probe is inserted into the 2cc cavity	System message	It provides instructions on proceeding with calibration	Press the Start key as instructed

ENTER PASSWORD	This message appears when attempting first-time access to the device calibration procedure, once the unit has been switched on	System message	It instructs you to enter your access password to unlock the device calibration procedure	Enter your password via the softkeys
WRONG PASSWORD	This message appears when attempting to access the device calibration procedure using a wrong password	System message	It means that you have entered the wrong password for access to the Calibration menus	Press the Enter key, then re-enter the password correctly
PARAMETERS CHANGED	This message is displayed upon startup of the device in the event that the system detects possible errors in one or more than one parameter relating to the test. The incorrect parameters will be displayed simultaneously with the message, on the same page	System message	It means that one or more than one of the files relating to the test parameters is either corrupt or missing	Press the Enter key. The corrupt files will be replaced with the system default files and it will then be possible to proceed using the device. If you are instructed to do so, it will be necessary to run the device calibration procedure

Maintenance and cleaning

- Clean the outer shell of the device using a clean, damp cloth (do not use aggressive detergent solutions). The penetration of liquids must be strictly avoided.
- During testing operations, headset pads and probe tips come into direct contact with the patient. Although said components are biocompatible, they are not sterile and they must therefore be subject to special care:
  – After each test session it is necessary to disinfect the headset pads before using them to test a new patient. To do so, use only commonly marketed non-allergenic disinfectant solutions and follow the directions supplied by the solution manufacturer.
  – The transducers and insertion headsets tips (Insert and Probe) are disposable: use only once and substitute them before use with a new patient.
  – After use of the probe it may occur that earwax (cerumen) has penetrated into the actual probe duct. Remove the earwax by unscrewing and cleaning both the conical part of the probe (where the tip is mounted) and the internal ducts, with the cleaning tools provided with the device. Strictly avoid tampering with the small tubes located internally to the probe, that are visible only once the conical part is removed.
  Refer to the Technical Manual for the complete description of the probe (226 Hz and HF) maintenance procedure.
- Calibration and any possible repair, installation and/or update of the device must be strictly carried out only by specialized technical personnel, duly authorized by the manufacturer and in full compliance with the terms and conditions specified in the Technical Manual.
- Standard maintenance and device calibration operations are to be regularly performed at one-year intervals. Standard maintenance operations cover the inspection of the transducer cable conditions, of the mains power supply cable, of the earphone pads as well as an inspection check to ensure the device's outer section and/or cabinet are in good working order. All device calibration operations must

be strictly performed only by qualified technical personnel, duly authorized by the manufacturer and implementing the appropriate apparatus for checking the levels and frequencies of all the output signals by the transducers supplied on-issue with the device. Once device calibration testing using the special purpose apparatus is complete, it is necessary to run a device function test.

- Device calibration is warranted by the manufacturer only if the transducers implemented are directly connected to the device.
- In the event of replacement of transducers and/or other device components, exclusive use of Original spares supplied directly by the manufacturer is highly recommended. Whenever transducers are replaced, recalibration of the device by qualified technical personnel is necessary.
- The device is provided with a lithium battery type CR2032 which enables constant updating of the date and time data displayed by the device. Said battery is welded onto the device PCB and possible replacement thereof must strictly be performed only by qualified technical personnel. Failure to observe this instruction may result in damages during battery replacement, thus preventing correct display of the date and time data by the device.
- Blown fuses must be replaced only with the same type of fuses, as specified on the device itself.

Maintenance and cleaning schedule

Daily	Weekly
• Presence of signals in the transducers provided • Correct probe signals operation using the calibration cavity provided • Probe cleanness*	• Good condition of all accessories cables and related jack-plugs • Compliance calibration*
Monthly	**Annually**
• General device condition • O-Ring probe status	• Perform calibration and routine maintenance check

*After every cleaning procedure performed on probe, the Compliance Calibration is mandatory.

Environmental conditions

Storage and handling	temperature range	from -20 °C to +50 °C / from -4 °F to +122 °F
	humidity range	from 20% to 80%, without condensation
	pressure range	from 500 hPa to 1060 hPa
Operating conditions	temperature range	from +15 °C to +35 °C / from +59 °F to +95 °F
	humidity range	from 30% to 90%, without condensation
	pressure range	from 700 hPa to 1060 hPa

Dimensions

- L x W x H: 370x290x180 mm Weight: 3.5 kg net

Power Supply

- 110-240 VAC 50/60 Hz 40 VA Fuses: 2 x T 1 A L 250 V

Reference Standards

- MDD 93/42/EEC and update 2007/47/CEE: Class IIa (as referred to in Annex IX, rule 10 of said MDD 93/42 EEC)
- Safety: to IEC 60601-1:2005 + AMD1:2012 Class 1 Type B
- EMC: to IEC 60601-1-2 (2012)
- Middle ear analyzer (Instruments for the measurement of aural acoustic impedance/admittance): to EN 60645-5; ANSI S3.39 Type 1
- Manufacturer quality system: to EN ISO 9001:2015 and UNI EN ISO 13485:2016 (Notified certification body: IMQ)

Tests

- Tympanometry (manual and automatic, absolute and compensated)
- Multifrequency Tympanometry (probe tones 678 Hz, 800 Hz, 1000 Hz. Y-B-G track visualization) "Children" function available with 1000 Hz probe tone
- Quick test options (two quick reflex and one quick decay test preceded by tympanometry, designed with rapid screening settings). "Children" function available for Quick Check Test.
- Special tests (Growth-DLI and Non acoustic)
- Reflex, Decay, ARLT (manual, automatic and threshold mode options with peak detection or at 0daPa)
- ETF (three test options: Eustachian tube functionality for both intact, perforated and patolous tympanic membrane)

Tympanometry

- Probe tone frequency: 226 Hz, 678 Hz, 800 Hz, 1000 Hz accuracy ±1%
- Probe tone intensity: 85 dB SPL ±2 dB (226 Hz); 75 dB SPL ±2 dB (678 Hz, 800 Hz, 1000 Hz)
- Pressure range: +400 daPa / –600 daPa adjustable in 50 daPa steps
- Pressure accuracy: ±10 daPa or ±10%
- Pressure generation speed (pump speed): 50, 100, 200, 300 daPa/s and Automatic
- Compliance range: 0.05 ml – 7 ml
- Compliance accuracy: ±0.1 ml or ±5%

Reflex, Decay and ARLT test max frequencies and max levels

	Tone (dB HL) - Noise (dB SPL)			
freq. (Hz)	IPSI (Probe)	IPSI (Probe HF)	CONTRA (DD45-TDH39)	CONTRA (Insert)
250	----	----	100	90
500	100	100	120	110
1000	105	105	120	110
2000	110	110	120	110
3000	105	105	120	110
4000	100	100	120	110
6000	----	----	115	105
8000	----	----	100	90
BBN	100	100	115	105
LPN	100	100	115	105
HPN	100	100	115	105

Reflex, Decay and ARLT tests

- Tone frequency accuracy: ±1%
- dB level variation: 1, 2, 5 or 10 dB

Stimulus duration (sec):

- Reflex: 0.5, 1 or 2
- Decay: 10
- ARLT: 1
- Non acoustic: 10 or 20

Technical descriptions more detailed and complete as wiring diagrams, parts list, instructions for calibration and other materials necessary for the repair and maintenance of the instrument, are contained in the service manual which will be provided, upon request, technical personnel authorized by the manufacturer to carry out such operations.

Models

SERIES	MODEL	CODE
R26M	R26M Diagnostic	4300105705
	R26M-ME Diagnostic	4300105720
	R26M-PT Diagnostic	4300105745
R36M	R36M Clinical	4300105805
	R36M-PT Clinical	4300105825

● = standard ○ = optional — = not available * = applied parts	FAMILY	
	R26M	R36M
ACCESSORIES		
Probe (226 Hz) or Probe HF (multifrequency – only PT models) *	●	●
Contralateral headband with DD45 or TDH39 *	●	●
Insert for Contra *	○	●
Kit tips	●	●
Calibration cavity	●	●
Thermal printer	●	●
Thermal paper roll	●	●
SD Card with Speech material	●	●
USB-Pen Drive with User Manual	●	●
Power supply cable	●	●
Device dust cover	●	●
Multilingual Quick user's handbook	●	●
USB Pen Drive	●	●
MDS software (demo version)	●	●
DHR documents regarding calibration data and CE compliance	●	●
External USB HUB Keyboard	○	○
Carrying bag	○	○
IP30 Insert earphones for Contra use*	○	○
MDS software License	○	○
TEST		
TYMPANOMETRY 226 Hz (R36M auto. and man. – R26M auto. only)	●	●
TYMPANOMETRY HF (only PT models)	●	●
REFLEX	●	●
DECAY	●	●
ETF (Perforated/intact)	—	●
ARLT	—	●
QUICK check (in "Children" mode); QUICK screening	●	●
Quick decay	—	●
NON ACOUSTIC (ETF Patulous)	—	●
GROWTH - DLI	—	●

Applied parts are constituted by the transducers that convey the test signals. Said transducers are applied so that they go into direct contact with the patient. In the foregoing list, they are highlighted in bold script and are counter-marked with an asterisk (*).

Following is a display of the transducers that constitute the applied parts of the device, with a description of the name and number of the relative connectors located on the unit's rear section for connection of the individual transducers.

Transducers for tympanometric tests

Probe
"Probe/Pressure" (16/17)

HF Probe
"Probe/Pressure" (16/17)

Contralateral headband
"Contra" (15)

Insert for Contra
" Contra" (15)

Insert earphones
"Contra" (15)

Electromagnetic emission

Guidance and manufacturer's declaration - Electromagnetic EMISSION		
The R26M/R36M middle ear analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the R26M/R36M should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR11	Group 1	The R26M/R36M uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR11	Class B	The R26M/R36M is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic Emissions IEC/EN 61000--3-2	Complies	
Voltage fluctuations/flicker emission IEC 61000-3-3	Complies	

Producer's guide and declaration - Electromagnetic IMMUNITY			
The R26M/R36M is suitable for use in the specified electromagnetic environment. The purchaser or user of the The R26M/R36M should assure that it is used in an electromagnetic environment as described below:			
Immunity test	IEC 60601-1-2 Test level	Compliance Level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2/4/8/15 kV air	IEC 60601-1-2 Test level	Floors should be wood. concrete or ceramic tile. If floors are covered with synthetic material. the relative humidity should be at least 30%.
Radiated electromagnetic field IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the R26M/R36M including cables. Recommended istance: $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the aximum power output of the transmitter in watt (W) based on the transmitter's producer and d is the recommended distance in meters (m).
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines > 3 m	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	0.5/1 kV differential mode 0.5/1/2 kV common mode	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 150 kHz to 80 MHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the R26M/ R36M including cables. Recommended distance $d = 1,2\sqrt{P}$

Voltage dips. short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Un for 0.5 cycle 0 % Un for 1 cycle 70 % Un for 25 cycles 0 % Un for 5 s	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the R26M/R36M requires continued operation during power mains interruptions. it is recommended that the R26M/R36M be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: At 80 MHz and 800 MHz, the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the R26M/R36M is used exceeds the applicable RF compliance level above, the R26M/R36M should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the R26M/R36M.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the R26M/R36M			
The R26M/R36M middle ear analyzer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the R26M/R36M can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the R26M/R36M as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 Khz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.2
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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Kamplex

r26m r36m

Middle ear analyser